TAB 5

510(K) SUMMARY

Date of Submission **12 September 2007**

Official Contact

Zita A. Yurko
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Classification Reference 21 CFR 868.5895; 21CFR 858.5905

Product Code CBK – Continuous Ventilator; BZD – non-continuous ventilator

Common/Usual Name Ventilator, continuous, facility use; ventilator, non-continuous (respirator)

Proprietary Name Respironics Performax SE Total Face Mask

Predicate Device(s) Respironics Total Face Mask (K992969) - BZD

Image 3 SE Face Mask (K023135) - CBK

Reason for submission new device

Substantial Equivalence

The Respironics Performax SE Total Face Mask has the following similarities to the previously cleared predicate device:

- ❑ Same intended use.
- ❑ Same operating principle.
- ❑ Same technology.
- ❑ Same manufacturing process.

This premarket notification submission demonstrates that the Performax SE Total Face Mask is substantially equivalent to the design of the Respironics Total Face Mask (K992969). Design modifications have been made to the Total Face Mask for this submission. These modifications are described here in. Based on the testing performed, none of the design modification affect the safety or effectiveness of the device.

The following changes have been made:

- The change in the face plate design to contour the face
- The change in the sealing cushion design
- The addition of a standard elbow without exhalation similar to the standard elbow used on the Image 3 SE. This design is intended for use with a ventilator that has an integral safety valve.
- The addition of the claim for multi-patient use to be included.

Intended Use

The Performax SE Total Face Mask is intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators which have adequate alarms and safety systems for ventilator failure, and which are intended to administer CPAP or positive pressure ventilation for treatment of respiratory failure, respiratory insufficiency or obstructive sleep apnea.

The mask is for multi-patient reuse on patients weighing > 30 kg), who are appropriate candidates for noninvasive ventilation, in the hospital/institutional environment only.

Device Description

The Respironics Performax SE Total Face Mask consists of a polycarbonate faceplate with silicon cushion seal for the face. Like the device predicate, Image 3SE full face mask (K023135), the interface to the patient circuit is a polycarbonate standard elbow. The design of the standard elbow (SE) is the same as the SE used on the Image 3SE Full Face mask. The mask when used with the standard elbow has one integrated exhalation feature, which includes one port on the faceplate. Similar to the device predicate, Total Face Mask (K992969), the mask faceplate contains headgear hooks upon which the premium headgear is attached. The mask is available in two sizes – small and large.

The Respironics Performax SE Total Face Mask is intended for use with a patient circuit that is used to connect the device to the patient interface device (mask). A typical patient circuit consists of a six-foot disposable or reusable smooth lumen 22mm tubing, a method of venting exhaled gases.

(End of Tab.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2007

Ms. Zita Yurko
Director, Regulatory Affairs
Respironics Incorporated, Sleep & Home Respiratory Group
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668

Re: K072588
Trade/Device Name: Respironics Performax SE Total Face Mask
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: November 21, 2007
Received: November 23, 2007

Dear Ms. Yurko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: ___Respironics Performax SE Total Face Mask_____

The Performax SE Total Face Mask is intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators which have adequate alarms and safety systems for ventilator failure, and which are intended to administer CPAP or positive pressure ventilation for treatment of respiratory failure, respiratory insufficiency or obstructive sleep apnea.

The mask is for multi-patient reuse on patients weighing > 30 kg, who are appropriate candidates for noninvasive ventilation, in the hospital/institutional environment only.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K072588